AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of Ohio

CITY OF CINCINNATI
Plaintiff
v.
AMERISOURCEBERGEN DRUG CORP. et al.
Defendant

Civil Action No. 2:17-cv-713

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: DEA Headquarters, ATTN: Alan N. Drumheller, ARCOS Unit Chief, 8701 Morrissette Drive, Springfield, Virginia
(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Appendix.

Place:	Date and Time:
Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.	TBD per Court Order

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/31/2017

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* City of Cincinnati, who issues or requests this subpoena, are:

Paul T. Farrell, Jr., Esq., 419 11th Street, Huntington, WV, 25705 (304-525-9115)

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 2:17-cv-713

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

☑ I served the subpoena by delivering a copy to the named person as follows: Mark T. D'Allessandro, U.S. Department of Justice, Assistant United States Attorney for the Southern District of Ohio as counsel for the Drug Enforcement Administration on *(date)* 10/31/2017 ; or

☐ I returned the subpoena unexecuted because: _____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: 10/31/2017

Server's signature

Paul T. Farrell, Jr., Esq.

Printed name and title

419 11th Street
Huntington, WV, 25705

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

APPENDIX

YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material:

1. Subject matter: Data from the Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[1] (69 FR 51104-02) national database in its native format, including all fields of information commonly stored, for the time period of January 1, 1995 to the present as limited and set forth in this Appendix

2. Source: Plaintiff is seeking production of ***limited*** data[2] contained within the ARCOS/DADS database. The information contained in this system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to ultimate consumers. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, receipts, purchase orders, and prescriptions, and include the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances. Information can be retrieved from this system of records by use of various data elements such as name, address, DEA registrant number, name of business, or social security number. The purpose of this system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. 69 FR 51104-02.

3. Context: All DEA registrants must "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

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[1] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017)

[2] Plaintiff has conferred with Mark T. D'Allessandro, U.S. Department of Justice, Assistant United States Attorney for the Southern District of Ohio, on behalf of the DOJ/DEA and encouraged to limit the scope of this subpoena. Plaintiff believes that additional data, other than hydrocodone and oxycodone sales, may be relevant to this litigation. However, in an effort to be transparent and deliberate, Plaintiff has limited the scope of this subpoena to only hydrocodone and oxycodone. If a need later arises for additional data, Plaintiff will consider additional requests.

Plaintiff asserts that certain distributors of prescription opioids failed to halt and report suspicious orders of hydrocodone[3] and oxycodone[4]. Plaintiff believes evidence of such conduct can be found in the ARCOS/DADS database. The data contained in the ARCOS/DADS system is ***relevant*** because it will reveal:

a. The usual size of orders nationally, regionally and locally as a baseline to determine orders of unusual size;

b. The normal pattern of orders nationally, regionally and locally as a baseline to determine orders deviating substantially from a normal pattern; and

c. The usual frequency of orders nationally, regionally and locally as a baseline to determine orders of unusual frequency.

See generally, Declaration of Joseph Rannazzisi, Cardinal Health, Inc. v. Eric Holder, United States District Court for the District of Columbia, Civil Action No. 1:12-cv-185 (RBW).

4. Timeframe: OxyContin is a prescription narcotic pain reliever that was approved by FDA in **1995**. Hence, the timeframe of this disclosure request dates back to the introduction of OxyContin into the United States market. The Federal Register defines a document retention policy for the requested data. 69 FR 51104-02. The DEA has informed the Court that it suspended its destruction of documents and has retained the same since 2006.

5. Response: The DEA is commanded to respond to this subpoena by filing with regard to its position on disclosure on or before November 15, 2017. **In no event shall the DEA produce documents until further order of the Court.**

6. Data requested: Plaintiff requests production of the ARCOS/DADS national database in its native format[5] related to the sale of hydrocodone and oxycodone by distributors to

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[3] "Hydrocodone" is a narcotic analgesic agent for the treatment of moderate to moderately severe pain and Schedule II controlled substance (DEA Controlled Substances Code No. 9193). There are several hundred brand name and generic hydrocodone products marketed, most of which are combination products. The most frequently prescribed combination is hydrocodone and acetaminophen (Vicodin®, Lortab®). Hydrocodone pills are the most frequently encountered dosage form in illicit traffic. Other trade names include Lorcet-HD®, Maxidone, Norco, Zydone, Hycodan® and Vicoprofen®.

[4] "Oxycodone" is a Schedule II narcotic analgesic (DEA Controlled Substances Code No. 9143) and is marketed either alone as controlled release (OxyContin®) and immediate release formulations (OxyIR® , OxyFast®), or in combination with other nonnarcotic analgesics such as aspirin (Percodan®) or acetaminophen (Percocet®). Other trade names include Endocet®, Roxicodone® and Roxicet®. Oxycodone is a widely prescribed in the U.S. and the controlled-release tablets are prescribed for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

[5] ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level. *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997. The subpoena requests the disclosure of the following details to access the ARCOS database:

- Database product name, version, latest service pack (i.e. Microsoft SQL Server 2012 SP3)
- Operating system required to run the database (i.e. Windows Server 2012)
- Any account username and password with appropriate permissions to

retailers/dispensers in the United States of America. Production should take the form of a searchable format[6] which enables the identification of the following data fields:

(a) the identity, address and DEA registrant number of the seller;
(b) the identity, address and DEA registrant number of the buyer;
(c) the date of the transaction;
(d) the name, quantity, and quality of the hydrocodone and/or oxycodone pills purchased; and
(e) summary reports involving these data fields.

Plaintiff intends to rely on this data production to calculate national, regional and local data to establish baselines, and specific deviations therefrom, related to the standards set forth in 21 C.F.R. § 1301.74(b) (see Touhy letter).

7. Reference: 21 U.S.C.A. § 823; 21 CFR 1301.74; 69 FR 51104-02; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017); *Madel v. US Dep. of Justice*, 784 F.3d 448 (8th Cir. 2015); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).

- observe all database meta data (such as lists of tables, views and stored procedures)
- query all relevant tables

- Any tools required to query the database
- Any relevant meta data required to understand
  - Where relevant data is stored (table and field names)
  - How tables are related
  - Any special information required to interpret the contents of relevant fields

[6] In the alternative to direct access to the ARCOS database and/or production of the database in its native format, Plaintiff is requesting the ability to search, filter and sort data in a functional format (e.g. Excel spreadsheet).